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AWARD NUMBER: DAMD17-00-1-0571

TITLE: Levels of Distress in Women with a Family History of Ovarian Cancer

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REPORT DATE: September 2005

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE *(DD-MM-YYYY)*	2. REPORT TYPE	3. DATES COVERED *(From - To)*
01-09-2005	Annual	1 Sep 2004 – 31 Aug 2005

4. TITLE AND SUBTITLE

Levels of Distress in Women with a Family History of Ovarian Cancer

5a. CONTRACT NUMBER

5b. GRANT NUMBER
DAMD17-00-1-0571

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Thomas Jefferson University
Philadelphia, Pennsylvania 19107

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

The overall goal of this study is to determine the levels of distress in women with a family history of ovarian cancer and to identify the mediating factors between risk of developing ovarian cancer and distress. The proposed study will use 180 first-degree relatives (FDR) of women diagnosed with ovarian cancer in a cross-sectional design. Information the ovarian cancer index case provides will be used to identify maternal relatives (mothers, sisters, or daughters). Women will be queried about their objective and subjective risk status, their knowledge of ovarian cancer and risk factors, their uncertainty about ovarian cancer, levels of anxiety and depression, their personality traits of mastery, tolerance for ambiguity, and optimism, and their interest in genetic testing. With the results generated by this study, the levels of distress could be identified and interventions could be designed and tested to improve adjustment of women at high risk for ovarian cancer.

We received IRB in August 2004 and Human Subjects approval from the DoD on May 31, 2005. The grant was transferred from Beth Israel Medical Center in New York City to Thomas Jefferson University in Philadelphia on March 15, 2005. To date we have recruited 17 women into this study with active recruitment ongoing.

15. SUBJECT TERMS
ovarian cancer; risk of ovarian cancer; risk factors; health behaviors; anxiety; depression

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
U	U	U	UU	11	19b. TELEPHONE NUMBER *(include area code)*

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Introduction

The overall goal of this study is to determine the levels of distress in women with a family history of ovarian cancer and to identify the mediating factors between risk of developing ovarian cancer and distress. The proposed study will use 180 first-degree relatives (FDR) of women diagnosed with ovarian cancer in a cross-sectional design.
Information the ovarian cancer index case provides will be used to identify maternal relatives (mothers, sisters, or daughters). Women will be queried about their objective and subjective risk status, their knowledge of ovarian cancer and risk factors, their uncertainty about ovarian cancer, levels of anxiety and depression, their personality traits of mastery, tolerance for ambiguity, and optimism, and their interest in genetic testing. With the results generated by this study, specific interventions may be designed and tested to improve adjustment of women at high risk for ovarian cancer.

Body

Work Accomplished as Related to Revised Statement of Work (approved) (see Appendix A)

Task 1 – All the items in Task 1 were accomplished. The PI, Dr. Kash moved from New York City to Philadelphia and assumed a position at Thomas Jefferson University in October 2003. The grant was transferred from Beth Israel Medical Center in New York City to Thomas Jefferson in March 2005. We received IRB approval at Thomas Jefferson University in August 2004 and approval from the DoD Human Subjects Review Committee on May 31, 2005.
Task 2 – We began recruiting women in June 2005 and to date have accrued 17 women. As described in Task 2 of the SOW, we are actively recruiting for this study.
Task 3 – Data is being entered as it is being collected into a SPSS database.

Problems in Accomplishing Tasks as related to Statement of Work

Since October 2003, the PI, Dr. Kash, has been at Thomas Jefferson University in Philadelphia. It took from October 2003 until March o f 2005 for Beth Israel Medical Center in New York City to transfer the grant. IRB approval from Thomas Jefferson University was received in August 2004. However it took an additional 10 months to receive approval from the DoD Human Subjects Approval Committee, which was received on May 31, 2005. At Thomas Jefferson University, one of the two members of the Gynecological/Oncology team left

Thomas Jefferson in July 2005, right when we received approval from the DoD to begin accrual. Despite this setback we have accrued 17 women since beginning two months ago. We have also received a continuing renewal of the grant from the IRB at Thomas Jefferson University. We do not anticipate any further issues to arise and we are actively recruiting for the study.

In summary, Task 1 has been completed and we have begun Tasks 2 and 3. None of the goals or objectives of the study have changed. The conceptual model for this study (*see Appendix B)* is the same as in the original proposal. We are moving forward and are actively recruiting women for this study.

Key Research Accomplishments
There have been none to-date.

Reportable Outcomes
There was an abstract presented about the conceptual framework which was submitted with our report in 2002. It is attached again in Appendix C.

Conclusions
We received approval of our protocol by the IRB in August 2004 and approval from the DoD Human Subjects Committee in May 2005. In March of 2005 the grant was officially transferred from Beth Israel Medical Center in new York City to Thomas Jefferson University in Philadelphia. We have accrued 17 women in a two-month period of time and are actively recruiting in order to obtain 180 participating in the study.

APPENDIX A

REVISED
STATEMENT OF WORK

LEVELS OF DISTRESS IN WOMEN WITH A FAMILY HISTORY OF OVARIAN CANCER

START: October 14, 2003
Items in bold are changes from the initial SOW.

Task 1. – Preparation of materials, data program, and training of staff - **Completed**

a. Measures are finalized.
b. Questionnaires copies.
c. Scripts for contacting potential participants are finalized.
d. Research Coordinator trained in recruitment procedure.
e. Codebook will be finalized.
f. Program for data entry will be written.

Task 2. – Recruitment of participants- **Month 10-21**

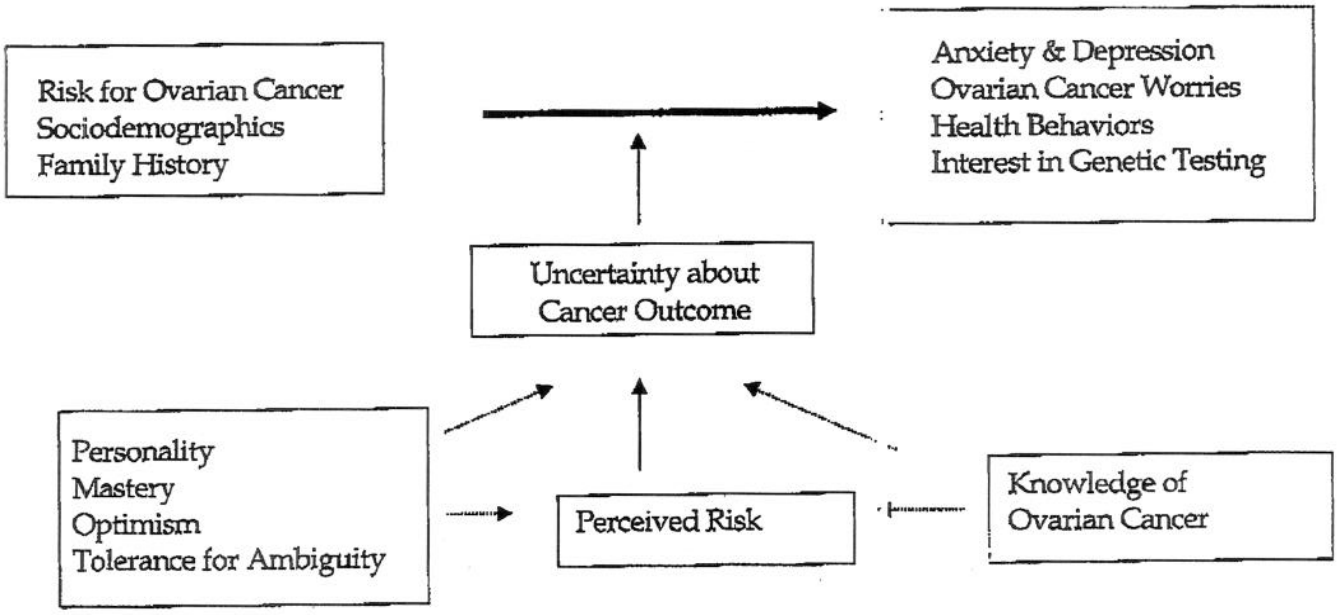
a. Index cases with diagnosed ovarian cancer will be sent a letter describing the study by the physicians in the Gynecologic Oncology practices at Thomas Jefferson University. The researchers will contact the index cases, if they do not opt out, within two weeks and provide more information about the study. Index cases will pass this information on to their sisters and daughters (FDRs) and have them contact the researchers directly if they are interested in participating. In addition, flyers will be placed in the Obstetrics and Gynecology practices at Thomas Jefferson university, at the Sandy Rollman Ovarian Cancer Foundation programs (for women only), advertising the study for women with a family history of ovarian cancer.
b. Contacted by unaffected female FDRs (total N=180).
c. Researchers speak with potential participants using telephone script to assess eligibility and determine interest in participation.
d. Study packet mailed to those interested in participation.
e. Participants contacted by telephone for interview completion after the informed consent has been returned.

Task 3. – Data entry and analysis - **Month 13-23**

a. Data entry is begun in month 13.
b. Preliminary data analyses are begun in month 21.
c. Final analyses are completed in month 23.

APPENDIX B

CONCEPTUAL FRAMEWORK



APPENDIX C

Levels of Distress in Women with a Family History of Ovarian Cancer

Kathryn M. Kash, Ph.D. & Mary Kay Dabney, M.S.
Beth Israel Medical Center, New York, NY, USA

Presented at the 7th International Meeting on Psychosocial Aspects of Genetic Testing for Heredity Cancer – Marseilles, France – March 2001

Introduction. There is evidence to suggest that women with a family history of ovarian cancer are at a higher than average risk for the disease and a small percentage are gene mutation carriers. To date, there have been no systematic studies of women who are at this increased risk because of their family history and the relationship between actual risk and levels of emotional distress as mediated by personality factors, perception of risk, and knowledge of ovarian cancer risk factors. Our proposal will envelope a much broader scope than previous work by looking at the distress associated with increased risk for ovarian cancer in FDR's (first-degree relatives) of index cases, rather than women attending screening clinics, which examining the predictor variables of such distress. We are particularly interested in how specific personality traits mediate level of distress. For example, one would expect that women who have a sense of mastery and optimism and better tolerance for ambiguity would be able to handle the uncertainty regarding being at increased risk for ovarian cancer and thus feel less distressed. In addition, we plan to look at the FDR's knowledge of genetic testing (as it relates to ovarian cancer). Perhaps the most serious limitation of genetic testing is that state-of-the-art diagnostics do not match test information. To receive positive genetic test results when there is no adequate screening is tragic.

Goals of Study. The overall goal of this study is to determine the levels of distress in women with a family history of ovarian cancer and to identify the mediating factors between risk of developing ovarian cancer and distress. With the results generated by this study, specific intervention can be designed and tested to improve adjustment of women at high risk for ovarian cancer.

Research Design. The proposed study will use 180 first-degree relatives (FDR) of women diagnosed with ovarian cancer in a cross-sectional design. Information the ovarian cancer index case provides will be used to identify maternal relatives (mothers, sisters, or daughters). Women will be queried about their objective and subjective risk status, their knowledge of ovarian cancer and risk factors, their uncertainty about ovarian cancer, levels of anxiety and depression, their personality traits of mastery, tolerance for ambiguity, and optimism, and their interest in genetic testing.